March 9, 2005

DoD Uniform Beneficiary Advisory Panel
c/o Mr. Richard Martel
TRICARE Management Activity
5111 Leesburg Pike, Suite 810
Falls Church, VA 22041

Messrs. Chairman and Members of the Panel:

I am submitting my statement as an interested party with a unique composite of perspectives on the issue of the Basic Core Formulary (BCF) determinations for the angiotensin receptor blocker (ARB) class. First, I am a DoD beneficiary enrolled in TRICARE Prime and receive the ARB, Cozaar (losartan potassium tablets) at my local Military Treatment Facility. Second, I am currently employed by Merck & Co., Inc., in its Federal Healthcare Affairs Department. Merck & Co., Inc. is maker of COZAAR (losartan potassium tablets). Finally, I served 26 years as a pharmacist in the Navy. During that period I held positions as Specialty Leader for Pharmacy to the Navy Surgeon General and later the DoD Pharmacy Program Director during the very period that the legislation that addressed the Uniform Formulary was passed by Congress.

Recognizing that the stated purpose of the Uniform Formulary (UF) was to create a "uniform, consistent and equitable pharmacy benefit" that will give adequate access to beneficiaries across the entire Military Health System, I am urging the Panel to ensure that the Basic Core Formulary (BCF) includes all ARBs that provide FDA-approved indications that are particularly relevant to the profiles commonly seen in Military Treatment Facilities. While all ARBs are indicated to treat hypertension, it should be noted that only COZAAR is indicated to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy, but there is evidence that this benefit does not apply to black patients. It is also important to consider that COZAAR is indicated to reduce the rate of progression of nephropathy as measured by the occurrence of doubling of serum creatinine or end stage renal disease in patients with type 2 diabetes, nephropathy and hypertension. Accordingly, I urge the Panel to recommend that the BCF for this class ensure an appropriate breadth of agents.

In an effort to provide balancing information, below you will find selective important information from the package insert for COZAAR. In addition, I have enclosed the complete prescribing information.

Thank-you for your consideration of these comments. Should you wish more information on this issue, I will be happy to respond to your questions.

Hypertension
COZAAR is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents, including diuretics.

Hypertensive Patients with Left Ventricular Hypertrophy
COZAAR is indicated to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy, but there is evidence that this benefit does not apply to Black patients. (See PRECAUTIONS, *Race* and CLINICAL PHARMACOLOGY, *Pharmacodynamics and Clinical Effects*, *Reduction in the Riskof Stroke*, *Race*.)

Nephropathy in Type 2 Diabetic Patients
COZAAR is indicated for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (urinary albumin to creatinine ratio ϒ⇑300 mg/g) in patients with type 2 diabetes and a history of hypertension. In this population, COZAAR reduces the rate of progression of nephropathy as measured by the occurrence of doubling of serum creatinine or end stage renal disease (need for dialysis or renal transplantation) (see CLINICAL PHARMACOLOGY, *Pharmacodynamics and Clinical Effects*).

COZAAR is contraindicated in patients who are hypersensitive to any component of this product.

USE IN PREGNANCY
When used in pregnancy during the second and third trimesters, drugs that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus.
When pregnancy is detected, COZAAR should be discontinued as soon as possible. See WARNINGS: *Fetal/Neonatal Morbidity and Mortality*.